REMARKS

Claims 1-33 and 35-61 are currently pending. Claims 9, 11, 41, and 43 have been cancelled. Claims 1, 10, 32, and 42 have been amended. Claims 1 and 32 have been amended to incorporate limitations from cancelled claims 9 and 41, respectively. Claims 10 and 42 have been amended so as not to depend from a cancelled claim. No new matter has been added by these amendments.

1. Rejection of the Claims under 35 U.S.C. §112, first paragraph

Reconsideration is requested of the rejection of claims 24 and 57 under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. In particular, the Office has stated that the specification does not teach how to use glucosylceramide (citing no amounts, weights or percentages given, and no discussion as to how it is incorporated into the tissue product claimed[1]).

MPEP 2163 states that "[t]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention." Furthermore, with regard to originally filed claims, it is well accepted that "a satisfactory

[1] Applicants assume the Office meant to refer to an absorbent product, since the claims of the present application are directed to absorbent products, not tissue products.

description may be in the claims or any other portion of the originally filed specification."[2]

Applicants note that glucosylceramide is set forth in claims 24 and 57 as originally filed. For instance, original claim 24 reads: "The absorbent product as set forth in claim 23 wherein the ceramide is glucosylceramide."[3] Written description support for glucosylceramide may therefore be found in original claims 24 and 57.

With regard to the Office's comments regarding amounts, weights, percentages, and method for incorporating glucosylceramide into the absorbent product, applicants respectfully note that in order to satisfy written description, the claimed invention must be described in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. Furthermore, subject matter that is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. Specifically, if a skilled artisan would have understood the inventor to be in possession of the claimed invention at the

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[2] MPEP §2163. *See also id.*, citing In re Koller, 613 F.2d 819 (CCPA 1980) (original claims constitute their own description); MPEP 2163.06 ("The claims as filed in the original specification are part of the disclosure."); MPEP §608.01(l) ("In establishing a disclosure, applicant may rely not only on the description and drawings as filed but also on the original claims if their content justifies it. Where subject matter not shown in the drawings or described in the description is claimed in the application as filed, and such original claim itself constitutes a clear disclosure of this subject matter, then the claim should be treated on its merits, and requirement made to amend the drawing and description to show this subject matter. The claim should not be attacked either by objection or rejection because this subject matter is lacking in the drawing and description. It is the drawing and description that are defective, not the claim.").

[3] Original claim 57 is similar, reading "The absorbent product as set forth in claim 56 wherein the ceramide is glucosylceramide."

time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met.[4] Applicants assert that one skilled in the art of skin care and skin care compositions would know the amounts, weights, percentages, and method for incorporating glucosylceramide into an absorbent product.

Furthermore, Applicants provide adequate description for one skilled in the art to conclude that Applicants had possession of the invention of using glucosylceramide in an absorbent product. Specifically, as disclosed in originally filed claims 24 and 57, glucosylceramide can be included in the moisturizing and lubrication composition. The composition is then incorporated into the absorbent product. More specifically, as described in paragraph 41 of the instant specification, the moisturizing and lubricating composition, which can optionally include ceramides such as glucosylceramide, is applied to the bodyfacing surface of absorbent products. Furthermore, as described in paragraph 79, the compositions are introduced onto the desired absorbent product in an amount sufficient to provide a moisturizing and lubricating benefit. For example, the moisturizing and lubricating compositions may be introduced onto the bodyfacing surface of an absorbent product in an amount of from about 0.05 g/m^2 to about 100 g/m^2, more preferably from about 1.0 g/m^2 to about 40 g/m^2, and even more preferably from about 4 g/m^2 to about 15 g/m^2.

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[4] *See, e.g.*, Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384 (Fed. Cir. 1986); Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563 (Fed. Cir. 1991); Martin v. Johnson, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972).

Based on the foregoing, possession is clearly shown by the disclosure of glucosylceramide in original claims 24 and 57. Furthermore, adequate description as to the amount and method of incorporating glucosylceramide into an absorbent product is provided by the description in the specification of amounts of moisturizing and lubricating composition that can be incorporated into the absorbent products. As such, Applicant's disclosure of glucosylceramide in the moisturizing and lubricating composition is sufficient to meet the written description requirement and, as such, this rejection should be withdrawn.

4. Rejection of the Claims under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claims 1-8, 10, 12-23, 25-33, 35-40, 42, 44-56, and 58-61 under 35 U.S.C. §103(a) as being unpatentable over Vega, et al. (U.S. Patent No. 6,153,209).

Amended claim 1 is directed to an absorbent product comprising an absorbent substrate and a moisturizing and lubrication composition. The moisturizing and lubricating composition comprises from about 1% (by weight) to about 40% (by weight) of an emollient, from about 1% (by weight) to about 20% (by weight) of a humectant, from about 30% (by weight) to about 90% (by weight) an immobilizing agent, and from about 1% (by weight) to about 40% (by weight) of a compatibilizing agent wherein no more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least

about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C. The immobilizing agent is a high molecular weight polyethylene glycol having the formula: $H(OCH_2CH_2)_xOH$, wherein x is the degree of ethoxylation and is an average value of at least about 20 moles.

Vega, et al. is directed to absorbent articles having a skin care composition deposited on at least a portion of the article. The skin care composition is a breathable, barrier protectant which can be immobilized on the article and is transferable to the wearer's skin via contact, normal wearer motion, and/or body heat. The skin care composition may comprise an emollient in an amount of from about 5 to about 95 wt.% of the skin care composition; an immobilizing agent in an amount of from about 5 to about 95 wt.% of the skin care composition, and optionally a humectant. Vega, et al. state that the compositions preferably fully melt at a temperature significantly above room temperature, and typically are applied to the article by heating the composition to a temperature in the range from about 35°C to about 150°C prior to application. Vega, et al. also state that the compositions preferably have a melt profile wherein 2-50% of the composition is liquid at room temperature (20°C).

Applicants respectfully submit that Vega, et al. fail to disclose a composition comprising the specific combination of an immobilizing agent that is a high molecular weight polyethylene glycol having the formula: $H(OCH_2CH_2)_xOH$, wherein x is the degree of ethoxylation and is an average value of at least about 20

moles, and from about 1% (by weight) to about 40% (by weight) of a compatibilizing agent. Nor is there any motivation in Vega, et al. to arrive at such a composition.

For instance, applicants maintain that Vega, et al. fail to even disclose a composition comprising from about 1% (by weight) to about 40% (by weight) of a compatibilizing agent. The Office has cited column 26, line 5 of Vega, et al. as disclosing compatibilizing agents. As the Office has correctly noted, Vega, et al. do disclose that their compositions may comprise propylene glycol, butylene glycol, and certain low molecular weight polyethylene glycols (e.g., PEG-2, PEG-3, etc.),[5] which may be considered compatibilizing agents.[6] Vega, et al., however, fail to teach or suggest the amounts of these agents that may be present in the compositions described therein, and in particular, fail to teach or suggest compositions comprising from about 1% (by weight) to about 40% (by weight) of these compounds or of compatibilizing agents generally.

Recognizing this deficiency, the Office has stated with regard to the claimed ranges, that "it would have been obvious…to determine suitable percentages through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art." Applicants respectfully disagree.

As noted in the specification of the present invention, the compatibility of the moisturizing and lubricating compositions of the present invention is important for the processability and

[5] *See* Vega, et al. at col. 26, lines 5-7, and col. 27, lines 48-49.
[6] *See* specification at p. 25, ¶67.

stability of the compositions. In particular, paragraph 66 of the specification states:

> Incompatible compositions require a more rigorous process to ensure that mixing is complete so as to prevent the separation of the different components in the composition. More mixing requires higher energy consumption, which leads to an increase in the cost of manufacturing the products. Further, it may be very difficult for an incompatible composition to maintain acceptable stability during the life of the product, starting with shipping, transportation, and storage prior to ultimate use by the consumer. Many incompatible ingredients may tend to slowly separate from the surface of the product to which they are applied resulting in a loss of the properties of the overall composition and a potential loss in the intended benefits.

The specification further states that certain components of the moisturizing and lubricating compositions, such as several of the immobilizing agents (e.g., high molecular weight polyethylene glycols), are incompatible with some humectants, such as glycerin.[7] Thus, in order to ensure a high degree of compatibility, the moisturizing and lubricating compositions include a compatibilizing agent. Compatibilizing agents are thus important for improving processing of the compositions, and to ensure good compatibility and a substantially homogenous composition.

None of these benefits of compatibilizing agents are disclosed or even recognized by Vega, et al. In particular, Vega, et al. merely list propylene glycol, butylene glycol, and certain polyethylene glycols as suitable humectants for use in

[7] *See* Specification at p. 25, ¶67.

their compositions.[8] Alternately, Vega, et al. state that propylene glycol and polyethylene glycols are suitable solvents for preservatives that may be included in the compositions.[9] There is, however, no disclosure of using propylene glycol, butylene glycol, or low molecular weight polyethylene glycols as compatibilizing agents, or of the need for compatibilizing agents generally.[10] Nor do Vega, et al. disclose suitable amounts of propylene glycol, butylene glycol, or low molecular weight polyethylene glycols for inclusion in their compositions. Consequently, why would one skilled in the art be motivated to determine the suitable amount of compatibilizing agent for inclusing in the compositions of Vega, et al. when Vega, et al. fail to disclose or suggest the need for such agents, and the only disclosed uses for propylene glycol, butylene glycol, and polyethylene glycols are as humectants and/or solvents for preservatives? While one skilled in the art may be able to optimize the amount of humectant to incorporate into the compositions of Vega, et al. based on the disclosure therein, one skilled in the art would not and could not be motivated to determine a suitable amount of compatibilizing agent for

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[8] *See* Vega, et al. at col. 26, lines 3-7.
[9] *See* Vega, et al. at col. 27, lines 48-49.
[10] In response to this statement, the Office has stated that the proposed benefits of compatibilizing agents is not essential to a determination of patentability of the composition disclosed in the claims. Applicants respectfully submit that the lack of disclosure in Vega, et al. of the benefits of compatibilizing agents is relevant. As pointed out in the above passage, one skilled in the art would not be motivated to optimize the amounts of propylene glycol, butylene glycol, or low molecular weight polyethylene glycols that are suitable for compatibilizing, as that use is not disclosed in Vega, et al.

inclusion in the compositions of Vega, et al. giving the lack of teaching or recognition of the benefits of doing so.

Furthermore, as amended, applicants claim 1 requires the immobilizing agent to be a high molecular weight polyethylene glycol having the formula $H(OCH_2CH_2)_xOH$, wherein x is the degree of ethoxylation and is an average value of at least about 20 moles.

The Office has cited to column 26, lines 6-7 of Vega, et al. as disclosing applicants' claimed immobilizing agents. However, the PEGs listed in this passage are low molecular weight PEGs that are disclosed as being useful humectants. In particular, Vega, et al. disclose PEG-2, PEG-3, PEG-30, and PEG-50. These are clearly not high molecular weight polyethylene glycol having the formula: $H(OCH_2CH_2)_xOH$, wherein x is the degree of ethoxylation and is an average value of at least about 20 moles, as required by amended claim 1.

Furthermore, in the response to arguments section, the Office has stated that high molecular weight PEGs are disclosed in U.S. Patent No. 4,556,660 (citing column 13, lines 6-11), and that this patent is incorporated into Vega, et al. by reference on column 26, line 64.[11] The '560 patent referred to by the Office discloses methods for the treatment and prevention of diaper rash and diaper dermatitis using the topical application of a lipase-inhibiting agent, e.g., a water-soluble metallic salt, applied in combination with a barrier-like vehicle. The ointment compositions described in the '560 patent may comprise

[11] Applicants assume the Office is referring to U.S. Patent No. 4,556,560, (not 4,556,660), as the '560 patent, not the '660 patent, is cited on column 26, line 64 of Vega, et al.

a mixture of short and long chain polyethylene glycols. In particular, column 13, lines 7-11 states that the high molecular weight polyethylene glycol polymers "have an average molecular weight of about 2,000 or greater, preferably about 3,000 or greater, and, more preferably about 4,000 to about 6,000."

Applicants respectfully note that the '560 patent is cited by Vega, et al. as describing a non-limiting example of skin care agents that may be used in the compositions of Vega, et al. As noted above, the "skin care agent" in the '560 patent is the lipase-inhibiting agent, not the high molecular weight polyethylene glycols. Nowhere do Vega, et al. state that the high molecular weight polyethylene glycols disclosed in the '560 patent should or could be used in their compositions as an immobilizing agent.

Furthermore, the '560 patent is only one of a large group of patents and applications cited by Vega, et al. as disclosing suitable skin care agents. More particularly, the '560 patent is merely one patent in a list of at least thirteen different patents and applications that Vega, et al. state disclose suitable skin care agents. Applicants respectfully submit that this is not a teaching by Vega, et al. to use high molecular weight polyethylene glycols as immobilizing agents in the compositions of Vega, et al.

Vega, et al. thus fail to disclose a composition comprising from about 1% (by weight) to about 40% (by weight) of a compatibilizing agent, and an immobilizing agent that is a high molecular weight polyethylene glycol having the formula:

$H(OCH_2CH_2)_xOH$, wherein x is the degree of ethoxylation and is an average value of at least about 20 moles.

Furthermore, there is nothing in Vega, et al. that would guide one skilled in the art to arrive at such a composition. For instance, in order to arrive at applicants' claim 1, one skilled in the art must pick and choose from a myriad of options in the Vega, et al. reference, without any guidance as to which options to choose to arrive at applicants' claim 1. At a minimum, one skilled in the art must choose, without the benefit of applicants' disclosure as a blueprint, two optional embodiments from Vega, et al. and combine these optional embodiments into a single embodiment.

Specifically one skilled in the art would have had to first decide to include propylene glycol, butylene glycol, or certain low molecular weight polyethylene glycols into the composition, all of which are listed in Vega, et al. as optional components in the compositions of Vega, et al.; specifically as suitable humectants or in the case of propylene glycol and polyethylene glycols, also as solvents for preservatives. After deciding to include one or more of these optional components, one skilled in the art would then have to determine the amount of propylene glycol, butylene glycol, or certain low molecular weight polyethylene glycols to include into the composition. However, as noted above, Vega, et al. do not disclose that any of these agents may be used as compatibilizing agents, or disclose the need for compatibilizing agents in general. Thus, the optimization of amounts for these agents must be done with no guidance by Vega, et al. as to what should be optimized.

One skilled in the art would then have to decide to select an immobilizing agent from a laundry list of thirteen patents and applications listed by Vega, et al. as disclosing optional skin care agents, with no guidance provided by Vega, et al. that suitable immobilizing agents are listed in any of those patents or applications, and then select the '560 patent from this list, again with no guidance by Vega, et al. to select this particular patent from the laundry list of thirteen patents and applications. One skilled in the art must then incorporate a high molecular weight polyethylene glycol as disclosed in the '560 patent into the composition as an immobilizing agent. Again, all this must be done with no guidance by Vega, et al. as to the benefits of a composition comprising the specific combination of from about 1% (by weight) to about 40% (by weight) of a compatibilizing agent and an immobilizing agent that is a high molecular weight polyethylene glycol having the formula: $H(OCH_2CH_2)_xOH$, wherein x is the degree of ethoxylation and is an average value of at least about 20 moles. Applicants respectfully submit that it is simply not obvious to make such a combination based on the lack of guidance provided by the disclosure of Vega, et al.

With all due respect, it appears that the Office has used impermissible hindsight analysis and reconstruction when modifying the cited reference. What is important is that there is no guidance provided by Vega, et al. to arrive at the specific combination of from about 1% (by weight) to about 40% (by weight) of a compatibilizing agent and an immobilizing agent that is a high molecular weight polyethylene glycol having the

formula: $H(OCH_2CH_2)_xOH$, wherein x is the degree of ethoxylation and is an average value of at least about 20 moles in a composition.

In light of the foregoing, applicants respectfully submit that claim 1 is patentable over Vega, et al.

Claims 2-8, 10, 12-23 and 25-31 depend directly or indirectly from claim 1 and are thus patentable for the same reasons as set forth above for claim 1 as well as for the additional elements they require.

As amended, independent claim 32 is directed to an absorbent product comprising an absorbent substrate and a moisturizing and lubrication composition comprising from about 1% (by weight) to about 40% (by weight) of a silicone, from about 1% (by weight) to about 20% (by weight) of a humectant, from about 30% (by weight) to about 90% (by weight) an immobilizing agent, from about 1% (by weight) to about 40% (by weight) of a compatibilizing agent and a dispersing agent wherein no more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C, and wherein the immobilizing agent is a high molecular weight polyethylene glycol having the formula: $H(OCH_2CH_2)_xOH$, wherein x is the degree of ethoxylation and is an average value of at least about 20 moles.

Claim 32 is patentable for the same reasons as set forth above for claim 1. In particular, Vega, et al. fail to disclose

or provide any guidance as to a composition comprising the specific combination of from about 1% (by weight) to about 40% (by weight) of a compatibilizing agent and an immobilizing agent that is a high molecular weight polyethylene glycol having the formula: $H(OCH_2CH_2)_xOH$, wherein x is the degree of ethoxylation and is an average value of at least about 20 moles in a composition.

Claims 33, 35-40, 42, 44-56, and 58-61 depend directly or indirectly from claim 32 and are therefore patentable for the same reasons as set forth above for claim 32 as well as for the additional elements they require.

4. Double Patenting Rejections

Claims 1-61 have been provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1-59 of copending Application No. 10/659,862.

Applicants note this rejection is in fact a provisional obviousness-type double patenting rejection since U.S. Patent Application No. 10/659,862 has not yet issued as a patent. Applicants will address the merits of these rejections, as appropriate, if the listed application issues as a patent before the application at hand.

CONCLUSION

In light of the foregoing, applicants request withdrawal of the rejections of claims 1-8, 10, 12-33, 35-40, 42, and 44-61 and allowance of all pending claims. The Commissioner is hereby authorized to charge any government fees which may be required to Deposit Account No. 19-1345.

Respectfully Submitted,

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